

Appl. No. 10/785,985
Amendment dated: April 19, 2006
Reply to OA of: January 19, 2006

REMARKS

This is in response to the Official Action of January 19, 2006.

Applicants acknowledge with appreciation the courtesy of the telephone interview extended the Applicants' representative by Examiner Chen, the Examiner in charge of this application. At the interview, the specification and claims of the instant application, the outstanding rejections of the claims and an appendix provided to the Examiner by Applicants' representative were discussed.

The interview began with discussion of the rejection of the claims under 35 U.S.C. §112, first paragraph for failing to comply with the enablement requirement. Applicants' representative attempted to argue that the specification and references referred to in the specification supported the claim language of an oral agent that prevents viral infection. The Examiner was unpersuaded by these arguments and suggested several alternative terms that could be used in the claim that would be supported by the specification and would overcome the §112, first paragraph rejection, including the term "inhibit".

Accordingly, Applicants have amended the claims of the instant application to replace the use of the term "prevent" with the use of the term "inhibit" as suggested by the Examiner. Claims 1, 14 and 19 now recite an oral agent that inhibits viral infection. In light of this amendment, Applicants respectfully submit that all claimed subject matter presented in the instant application is described in the specification in such a way as to enable one of ordinary skill in the art to make and use the invention. It is therefore respectfully requested that the rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. §112, first paragraph be withdrawn.

After discussing the §112 rejection, the interview shifted to discussion of the §102 and §103 rejection of the claims over the Hirahashi, Gemma and Hayashi references. Applicants' representative began by noting the statement made in the Official Action that Spirulina naturally contains C-phycocyanin (CPC), allophycocyanin (APC) and spirulina growth factor (SGF), and that no citation was provided in the Official Action for where in the references such an assertion was supported. After reviewing the references, the

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Examiner acknowledged that none of the references cited appeared to support this assertion. Because none of the cited reference supported the assertion that *Spirulina* naturally contains CPC, APC and SGF, Applicants' representative noted that it naturally follows that none of the references disclose the specific ranges of these components claimed in the oral agent of the present application. The Examiner acknowledged that because the references did not support the assertion that *Spirulina* naturally contains CPC, APC and SGF, the burden to support this assertion could be placed on the Examiner in Applicants' response to the Official Action. In the meantime, the Examiner agreed to attempt to find the reference used in support of this assertion that was perhaps inadvertently left out of the Official Action, and to contact Applicants' representative with any references uncovered by the Examiner.

Shortly after the interview concluded, the Examiner sent to Applicants' representative the initial results of her search for a reference supporting the assertion that CPC, APC and SGF naturally occur in *Spirulina* in concentrations that fall within the ranges claimed in the present invention. Three references were provided to Applicants' representative.

The reference entitled "Purification, Crystallization and Preliminary X-ray Diffraction Studies of C-Phycocyanin and Allophycocyanin from *Spirulina platensis*" discloses that C-phycocyanin and Allophycocyanin are found in *Spirulina platensis*. However, no mention is made of the concentration of these components in *Spirulina platensis* nor does the reference make any disclosure as to SGF.

The reference entitled "Spirulina's Nutritional Analysis" discloses that phycocyanin is found in *Spirulina* at a concentration of about 7%. The reference makes no mention of CPC, APC, SGF or their concentrations in *Spirulina*.

The reference entitled "Spirulina" discloses that *Spirulina* contains phycocyanin and allophycocyanin. There is no disclosure in the reference as to the concentration of allophycocyanin in *Spirulina*. There is no disclosure in the reference as to the presence and concentration of C-phycocyanin or SGF in *Spirulina*. Further, this reference suggests that phycocyanin and allophycocyanin are separate components and therefore

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suggests that the teaching in the reference entitled "Spirulina's Nutritional Analysis" that Spirulina may contain 7% phycocyanin does not disclose the concentration of CPC or APC in Spirulina.

The rejection of claim 1, 2, 14 and 16 under 35 U.S.C. §102(b) as being anticipated by Hirahashi et al. and the rejection of claims 1, 2, 14, 16 and 19 under 35 U.S.C. §102(b) as being anticipated by Gemma et al. have been carefully considered but are most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Official Action urges in the §102 rejection of the claims over Hirahashi and the §102 rejection of the claims over Gemma that *Spirulina* naturally contains C-phycocyanin, allophycocyanin and spirulina growth factor. However, as discussed above and as acknowledged by the Examiner during the interview, neither of the references expressly disclose or provide support for this assertion. For this reason, Applicants respectfully traverse these rejections.

Even when considering the three references provided to Applicants after the interview, there is still a lack of support for the position that Spirulina contains CPC, APC and SGF. As discussed above, the references at best disclose the presence of APC and CPC in Spirulina. But none of the references discuss concentration ranges as

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claimed in the instant application and none of the reference even mention the presence of SGF in Spirulina, let alone its concentration.

Applicants respectfully submit that the burden is initially on the Examiner to show how the cited references disclose every element of the claimed invention in order to properly establish a §102 rejection according to the guidelines set forth in MPEP §2131. While the Examiner has made assertions in the Official Action as to the naturally occurring components of Spirulina, the Examiner has not provided adequate support for these assertions. Specifically, no reference brought to the attention of Applicants has yet to clearly show that CPC, APC and SGF all naturally occur in Spirulina. Absent such a showing, Applicants respectfully submit that a proper §102 rejection has not been established, and therefore the rejection should be withdrawn.

Furthermore, even if it is eventually established by the Examiner that CPC, APC and SGF occur naturally in Spirulina, Applicants respectfully submit that the Examiner must also carry the burden of providing support that these components naturally occur in Spirulina in the claimed ranges. Up to this point, the Official Action has merely urged that because the claimed ranges are broad, the naturally occurring CPC, APC and SGF would be expected to fall within the claimed ranges. However, no support is provided for this assertion. It appears to merely be a statement as to probability based on an assumption as to what constitutes a broad range of concentrations.

While the Official Action may be correct in its characterization of the claimed ranges as broad, this does not detract from the fact that the ranges claimed may still be outside of the concentration ranges of CPC, APC and SGF as they naturally occur in Spirulina. Specifically, Applicants note the claimed range of 40-96% SGF in the claimed oral agent. While this claimed range may be broad, Applicants note that the range excludes all concentrations below 40%. This too is a broad range of excluded concentration. Therefore, it is just as likely that SGF occurs in only trace amounts in Spirulina and therefore falls well outside of the claimed range as it is that the SGF occurs in large amounts in Spirulina and therefore falls well within the claimed range.

However, the bottom line is that the burden initially lies with the Examiner to

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provide support for the conclusion that the claimed components not only naturally occur in *Spirulina* but also occur in the claimed concentrations. A statement such as the one made in the Official Action that because the claimed ranges are broad, one would expect the components to naturally occur in a concentration that falls within the claimed range does not suffice to meet the requirements for properly establishing a §102 rejection. Applicants respectfully submit that more than a mere expectation is necessary to reject the claims under §102. Absent an express disclosure that the assertions made in the Official Action with respect to the concentration ranges have support in the art, Applicants respectfully submit that the §102 rejection should be withdrawn.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. §103(a) as being unpatentable over Hirahashi or Gemma in view of Hayashi et al. (US Pat No. 5,585,365) has been carefully considered but is most respectfully traversed in light of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a *prima facie* case of obviousness as set forth in the MPEP § 2143. This section states that to establish a *prima facie* case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an

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independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

As discussed in detail above, Applicants respectfully submit that the Official Action has not carried its burden to provide support for the assertion both that CPC, APC and SGF occur naturally in Spirulina and that these components occur naturally in Spirulina in the concentrations claimed in the present invention. The Hayashi reference fails to remedy this deficiency. Hayashi is relied upon to disclose Spirulina extracts formulated into tablets, but like Gemma and Harahashi, there is no express disclosure in Hayashi as to the components that naturally occur in Spirulina or their natural concentrations. Accordingly, as none of the prior art references, either standing alone or when combined, disclose or suggest every element of the claimed invention, Applicants respectfully submit that a proper §103 rejection according to the guidelines set forth in MPEP §2143 has not been established. It is therefore respectfully requested that this rejection be withdrawn.

Further, the present application contains claims directed to not only the percentage of C-phycoyanin, allophycocyanin and spirulina growth factor in the oral agent, but also to their concentration ranges (claims 11 and 12), the ratio of water-soluble formula to enteric-coated formula (claims 3 and 4) and ratio of the total amount of C-phycoyanin and allophycocyanin to spirulina growth factor (claims 13 and 15). The Official Action makes no reference to these limitations and therefore fails to show where in the prior art references such limitations are disclosed or suggested. Applicants respectfully assert that no such disclosure or suggestion exists in the prior art references. As discussed above, the prior art references discuss only the use of Spirulina and fail to address the components of C-phycoyanin, allophycocyanin and spirulina growth factor. Thus, Applicants assert that the references clearly fail to teach these specific limitations. Because neither Gemma, Hirahashi nor Hayashi, either standing alone or in combination, disclose or suggest every element of the presently amended claims, the references cannot properly support a §103(a) rejection. Accordingly, Applicants respectfully request that this rejection be withdrawn.

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Finally, Applicants respectfully assert that the ratio of water-soluble formula to enteric-coated formula recited in the present claims and the ratio of the total amount of C-phycoerythrin and allophycoerythrin to spirulina growth factor recited in the present claims are novel and non-obvious. Applicants respectfully assert that it would not have been obvious to one of ordinary skill in the art to come to these ratios. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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